3M NEXCARE COLD SORE TREATMENT- benzocaine and allantoin ointment 3M Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Nexcare™ Cold Sore Treatment

- Unique combination of ingredients
- Helps relieve cold sore symptoms
- Enriched with tea tree oil and Vitamin E
- Helps get you back to living comfortably

Drug Facts

Active Ingredient

Benzocaine, 5%

Allantoin, 1%

Purpose

External analgesic

Skin protectant

Uses

- temporarily relieves pain and itching associated with cold sores and fever blisters
- relieves dryness and softens cold sores and fever blisters

Warnings

For external use only

Do not use if you are allergic to any ingredient in this product

When using this product do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older:
- apply directly to affected area with clean finger at the first sign of cold sore/fever blister (tingle)
- apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Other information

• store at 20-25°C{68-77°F}

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, butylated hydroxytoluene, cetyl alcohol, edetate disodium, ethyl oleate, ethylparaben, glycerin, melaleuca alternifolia (tea tree) leaf oil, menthol, methylparaben, phenoxyethanoi, poloxamer 185, propylparaben, propylene glycol monolaurate

(MicrovexTM), sodium ascorbyl phosphate, sodium hydroxide, tocopheryl acetate, water

Questions?

Call 1-800-537-2191

3M, Nexcare and Microvex are trademarks of 3M.

3M Consumer Health Care

3M Center St. Paul, MN 55144-1000 www.nexcare.com

Made in the U.S.A. for 3M from globally sourced materials.

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Patent Pending

Package Label

1 Tube

NET WT 2g (0.07 oz)

3MTM NexcareTM Cold Sore Treatment

Benzocaine 5% Allantoin 1 %

Skin Protectant

OTC Monograph

3M Consumer Health Care, 3M Center, St. Paul, MN 55144-1000

3MTM NexcareTM Cold Sore Treatment - NET WT 2g (0.07 oz)





3M NEXCARE COLD SORE TREATMENT

3m nexcare cold sore treatment ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17518-054
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Benzocaine (UNII: U3RS Y48 JW5) (Benzocaine - UNII: U3RS Y48 JW5)	Benzocaine	50 mg in 1 g	
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	10 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
butylated hydroxytoluene (UNII: 1P9 D0 Z171K)		
cetyl alcohol (UNII: 936JST6JCN)		
edetate disodium (UNII: 7FLD91C86K)		
ethyl oleate (UNII: Z2Z439864Y)		
ethylparaben (UNII: 14255EXE39)		
glycerin (UNII: PDC6A3C0OX)		
menthol (UNII: L7T10EIP3A)		
methylparaben (UNII: A2I8C7HI9T)		
phenoxyethanol (UNII: HIE492ZZ3T)		
propylparaben (UNII: Z8 IX2SC1OH)		
propylene glycol monolaurate (UNII: M4AW13H75T)		
sodium ascorbyl phosphate (UNII: 836SJG51DR)		
sodium hydroxide (UNII: 55X04QC32I)		
sucralose (UNII: 96K6UQ3ZD4)		
water (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-054-01	2 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	02/20/2008		

Labeler - 3M Company (006173082)

Establishment				
Name	Address	ID/FEI	Business Operations	
Celeste Contract Packaging		829739833	MANUFACTURE	

Revised: 2/2010 3M Company